

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Inventor : DALEY
Appln. No. : 09/670,781
Conf. No.: : 6751
Filed: : September 27, 2000
Title: : SYSTEM, METHOD AND PACKAGE FOR PROVIDING A
LIQUID SOLUTION

Group Art Unit : 1761
Examiner : WEINSTEIN, S.
Docket No. : 011149US1

**MS Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

ATTENTION: Board of Patent Appeals and Interferences

REPLY BRIEF (37 C.F.R. § 41.37)

This Reply Brief responds to the Examiner's April 21, 2009 Answer in the appeal of the above-captioned application, and is being timely filed within two months of the date of the Examiner's Answer.

The Examiner's Answer predominantly repeats the rejections from the March 13, 2006 Final Office Action without responding to Appellant's arguments in Appellant's March 20, 2009 Appeal Brief. Thus, Appellant limits this reply to addressing the instances where the Examiner has substantively responded to the arguments and evidence in March 20, 2009 Appeal Brief.

I. ARGUMENT

- A. **The rejection of claims 1-4, 6, 7, 10, 21, and 23-36 under 35 U.S.C. § 103(a) as obvious over Lazure in view of the AAPA, the Stevens 1997 article, the Stevens 1999 article, the Franck article, further in view of Beckers, and Hendriks, Bublitz, further in view of the Seattle Post-Intelligencer article, Wisconsin State J. article, further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine**

Claims 1-4, 6, 7, 10, 21, and 23-36 were rejected under 35 U.S.C. § 103(a) as obvious over Lazure in view of the AAPA, the Stevens 1997 article, the Stevens 1999 article, the Frank

article, further in view of Beckers, and Hendriks, Bublitz, further in view of the Seattle Post-Intelligencer article, Wisconsin State J. article, further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine.

Appellant traverses this rejection based on the reasons and supporting evidence in Appellant's March 20, 2009 Appeal Brief. Appellant specifically traverses the Examiner's Answer for the following reasons.

1. The Examiner's Answer Improperly Disregarded Appellant's Teaching Away Argument

In general, the pending obviousness rejection is based on the Office Action's assertion that because (1) "the application of a single serve or single use cups for all type of products, edible, medicinal and inedible, in all sizes and shapes of cups, is notoriously conventional in the art of packaging" (see, e.g., Lazure, Hendriks, Beckers), and (2) "sugar solutions have been formulated to use as a pain relief/calming medium for infants" (see, e.g., Blass, Stevens 1999, Stevens 1997, Frank), it would have been obvious to use such single cups to store medicinal sugar solutions, and that such a modification would result in the combination of recitations in the claims. 7/13/05 Office Action, pp. 2-3; 3/13/02 Office Action, p. 3.

As explained in Appellant's March 20, 2009 Appeal Brief, Lazure teaches away from the proposed combination by specifically teaching the use of precisely measured "unit doses of medicine" in a container. *See* Lazure, col. 1, lines 5-6. The purpose of such "unit dose" containers of medicine is to ensure that a patient is administered a correctly measured dose of medicine, thereby avoiding overdosing or underdosing.

The asserted sucrose solution references teach that only a very small dose of sucrose solution (e.g., from 0.05 to 2 ml) is ever administered to a newborn patient. *See, e.g.,* Franck, p. 1 ("Two milliliters of 24% sucrose solution....;" "smaller doses of sucrose (as little as 0.05 ml)"); *see also id.* at p. 2 ("Only a very small drop (less than .05 ml) of the sucrose solution administered by syringe, dropper, or pacifier is needed.").

Lazure expressly teaches away from the Office Action's proposed placement of such sucrose solutions into Lazure's unit dose containers for two reasons.

First, because an appropriate unit dose sucrose solution is so small, if it were placed in Lazure's container, it would be difficult or impossible to administer the entire unit dose to a

patient. For example, it would be difficult or impossible to transfer the entire unit dose from in the container to a pacifier for subsequent administration to a patient, particularly in view of how small a unit dose of such a sucrose solution is. Thus, the proposed combination would prevent or seriously impair a physician's ability to administer a full unit dose of sucrose solution to a patient. Such an underdosing result entirely defeats the purpose of "unit dose" teachings such as Lazure. *See* MPEP 2143.01(V) ("If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."). Moreover, the resulting additional hassle associated with attempting to administer the entire contents of the container are antithetical to the convenience goal of Lazure's "unit dose" container.

Second, to the extent that the pending rejection is based on the assertion that it would have been obvious to fill Lazure's container with more than a unit dose (Appellant disputes the obviousness of this), the resulting combination would no longer contain a unit dose of medicine. Such a result is again antithetical to Lazure's "unit dose" teaching because it defeats the exact unit dose goal of Lazure, and could result in the overdosing that "unit dose" containers seek to prevent. *See* MPEP 2143.01(V) ("If proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."). Put another way, the proposed combination is nonobvious because it would change the Lazure's principle of operation, i.e., the use of a "unit dose" container to ensure the convenient administration of a correct dose of medication. *See* MPEP 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").

The Examiner's Answer disregards the above teaching away argument on the ground that "claim 1 does not recite a unit dose portion." Examiner's Answer at 5-6; *see also id.* at 10 ("[M]any of the urgings that have been made are directed to limitations not found in the claims. Urgings are made that are directed to single use containers..."). However, Appellant's product and claim limitations are entirely irrelevant to Appellant's "teaching away" argument, which depends only on the nonobviousness of the prior art combination itself, specifically Lazure and the proposed modification to Lazure. Thus, the Examiner's disregard for Lazure's teaching

away from the proposed combination was improper and cannot form the basis of a *prima facie* case of obviousness.

The Examiner's Answer also improperly disregards the teaching away argument on the ground that the office action merely relied on Lazure as "a general teaching." Examiner's Answer at 5. However, use of a reference as a "general teaching" does not excuse the Examiner from considering other portions of Lazure that explicitly teach away from the proposed combination, particularly because Lazure is the primary cited reference. Indeed, the Examiner's argument shows that the Examiner has intentionally and improperly failed to consider Lazure as a whole. See MPEP 2141.03(VI) ("A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.") (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)) (underlining in original).

The Examiner's Answer also responds to Appellant's teaching away argument by asserting that "it would have been obvious to provide unit portions, rather than bulk portions." Examiner's Answer at 6. That only confirms Appellant's argument that Lazure teaches the use of unit doses and teaches away from containing non-unit doses in Lazure containers, as would result from the proposed combination.

Thus, Lazure teaches away from the proposed combination, and the Examiner's Answer does not adequately or properly respond. The Examiner has therefore not provided a *prima facie* case of obvious for at least this reason.

2. Redundant Citation to Cumulative Prior Art Does Not Render Obvious An Unknown Modification To That Prior Art

The Examiner's Answer asserts that the strength of the rejection is bolstered by the sheer number of references included in the rejection. See Examiner's Answer at 7 (asserting that "where teachings relied upon to show obviousness were repeated in a number of references, the conclusion of obviousness was strengthened."). However, these numerous cumulative prior art references show only that (a) it was known to administer a sucrose solution to an infant, and (b) it was known to use unit dose medicinal containers. None of them provide the missing motivation or suggestion to make the combination proposed by the Examiner. Nor was there any other obvious rationale to have made the combination.

In fact, it is submitted that the presence of many references in the same field, where all of those lack the new teaching being claimed, is highly indicative of non-obviousness.

3. Passage of time exhibits a trend away from the present invention

Appellant explained in the March 20, 2009 Appeal Brief how the “trend” in the art away from the claimed invention evidences its nonobviousness. *See* 3/20/09 Appeal Brief at 11-12; *see also Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 45 USPQ2d 1977 (Fed. Cir. 1998). The Examiner’s Answer disregarded this trend on the ground that “patentability is predicated on what the art teaches, not at any one date or one of the references, but what the art, taken as a whole, teaches at the time of applicant’s invention.” Examiner’s Answer at 12. However, the Examiner’s disregard for this evidence is improper in view of *Monarch*, and cannot, therefore, form the basis of a proper *prima facie* case of obviousness.

4. The Examiner’s Answer Improperly Disregarded Compelling Objective Evidence Of Nonobviousness Of Claims 1-4, 6, 7, 10, 21, and 23-36

As explained on pages 13-20 of Appellant’s March 20, 2009 Opening Appeal Brief, the objective evidence of nonobviousness (including an infringer’s adulation for the claimed invention, the commercial success of the claimed invention, and a long-felt but unmet need for the claimed invention) compels reversal of the pending obviousness rejection.

Moreover, as explained below, the Examiner’s Answer improperly disregarded this evidence for legally unsound reasons. Such disregard for objective evidence requires reversal for this procedural ground as well. *See In re Sullivan*, 498 F.3d 1345, 1351, 84 USPQ2d 1034, 1038 (Fed. Cir. 2007) (remanding finding of obviousness by Board of Patent & Appeals under *KSR* for failing to adequately consider secondary evidence of nonobviousness).

a. The Examiner Cannot Disregard Adulation, Commercial Success, and Long-Felt Need Evidence Based On A Subjective, Hindsight Belief That Such Evidence Is “Expected”

The Examiner’s Answer systematically disregarded all of Appellant’s objective evidence on the ground that the objective evidence failed to “present any unexpected evidence.” Examiner’s Answer at 12-13; *see also id.* at 13 (disregarding commercial success evidence because “one would expect sales [of the claimed invention] to be better for the well recognized sucrose analgesic solution” and “the convenience of single use containers ... is not an unexpected result. It is an expected result.”) (underlining added); *id.* at 14 (disregarding long felt

need evidence because, “[a]s noted several times above, these are expected results and not unexpected results.”) (underlining added).

However, as explained to the Examiner in Appellant’s March 20, 2009 Appeal Brief, the relevance and weight of the submitted objective evidence of an infringer’s adulation for the claimed invention, the commercial success of the claimed invention, and a long-felt but unmet need for the invention does not depend in any way on such evidence being “unexpected.” See 3/20/09 Opening Appeal Brief at 16-17 and 19-20. Nor does the Examiner’s subjective, hindsight, “expected result” assertion rebut any of Appellant’s objective evidence. Indeed, the submitted evidence provides objective proof that the Examiner’s hindsight allegation is wrong, or else others would have previously obtained the commercial success for themselves and satisfied the long-felt need themselves. Indeed, the very difference between this objective evidence of nonobviousness and the Examiner’s subjective, hindsight belief is why such objective evidence provides “virtually irrefutable” proof of the nonobviousness of the claimed invention. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099, 227 U.S.P.Q. (BNA) 337, 348-49 (Fed. Cir. 1985); *see also Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960, 1 USPQ.2d (BNA) 1196, 1199 (Fed. Cir. 1986) (“[O]bjective evidence **must be considered**. It can be the most probative evidence of nonobviousness in the record and enables the district court to avert the trap of hindsight.”) (emphasis added); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39, 218 USPQ (BNA) 871, 879 (Fed. Cir. 1983) (“[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not.”).

b. The Examiner’s Answer Improperly And Completely Ignored Appellant’s Adulation Evidence

The law recognizes that praise or adulation of the claimed invention by others is indicative of nonobviousness. See *Libbey-Owens-Ford Co. v. BOC Group Inc.*, 655 F. Supp. 897, 914, 4 USPQ.2d (BNA) 1097, 1109 (D. N.J. 1987) (“[S]tatements of praise by the [accused infringer] made prior to the initiation of litigation are a strong indication of the non-obviousness of [the] invention.”); *see also Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ.2d (BNA) 1378, 1384 (Fed. Cir. 1997) (holding that an infringer’s “recognition of the importance of [the patented invention] is relevant to a determination of nonobviousness”);

Minnesota Mining & Manufacturing v. Smith & Nephew PLC, 25 USPQ.2d (BNA) 1587, 1592 (D. Minn. 1992) (“Insofar as [the accused infringer's marketing] information lends insight into a defendant's actual beliefs about the relative uniqueness, superiority and marketability of a disputed patent, it has been recognized as valuable in evaluating a defendant's public assertions that a patent was obvious and therefore invalid.”).

As explained and proved in Appellant’s March 20, 2009 Appeal Brief and supporting evidence, Appellant’s direct competitor, Hawaii Medical, LLC, prominently advertises and promotes the presently claimed invention through its advertisement for its TootSweet product (attached as Evidence Exhibit D). See 3/20/09 Appeal Brief at 14-15. Such adulation for the presently claimed invention clearly demonstrates that even Appellant’s competitor recognized the uniqueness, marketability, and value of the presently claimed invention. Such adulation by an unbiased and independent third party is “a strong indication of the non-obviousness of [the] invention.” *Libbey-Owens-Ford*, 655 F. Supp. at 914, 4 USPQ.2d at 1109.

The Examiner’s Answer improperly and completely failed to consider or address such adulation evidence.

c. The Office Action’s failure to weigh the objective evidence as a whole against the alleged *prima facie* case necessitates reversal

A review of the Examiner’s treatment of the Appellant’s objective evidence in general shows that, in essence, to the extent the Examiner substantively considered the evidence at all, the Examiner considered each individual piece of rebuttal evidence for its ability to “knock down” the alleged *prima facie* case of obviousness, which is legally impermissible. *In re Piasecki*, 745 F.2d 1468, 1472-73, 223 USPQ 785, 788 (Fed. Cir. 1984). Instead, when rebuttal evidence is presented, any *prima facie* case of obviousness is dissipated, and all the evidence must be reconsidered in reaching the final conclusion on the issue of obviousness. *Id.*, 745 F.2d at 1472-73, 223 USPQ at 788. That is, the presentation of rebuttal evidence eliminates the procedural presumption afforded to the alleged *prima facie* case, and all the evidence must be reconsidered anew in its entirety. *Id.*, 745 F.2d at 1472-73, 223 USPQ at 788.

Here, however, it is clear from the record that the Office Action and Examiner’s Answer did exactly what the Federal Circuit prohibits, and analyzed each individual category of rebuttal evidence submitted by Appellant for its ability to “knock down” or overcome the alleged *prima facie* case of obviousness. Nothing in the record indicates that the Examiner ever considered the

totality of the rebuttal evidence as a whole. And nothing in the record indicates that the Examiner ever set the alleged *prima facie* case aside and reconsidered all the evidence anew. Instead, for each category of such rebuttal evidence, the record is clear that the Examiner simply analyzed it alone and discounted it as being insufficient to rebut what the Examiner considered to be the *prima facie* case, allowing the Examiner's *prima facie* case to remain impermissibly "set in concrete." *Id.*, 745 F.2d at 1472, 223 USPQ at 788. There was not a single indication in the record that the Examiner took the proper approach and considered all the evidence (both for and against obviousness) anew in its entirety, as is legally required. Thus, the approach taken by the Examiner with respect to the objective evidence is exactly the approach prohibited by *In re Piasecki*.

Appellant is entitled to have the objective evidence considered in its entirety and in a procedurally proper manner. Here Appellant not only submits that the Office Action and Examiner's Answer reached the wrong substantive conclusion on obviousness, but that they also did so in a procedurally improper way. *See In re Sullivan*, 498 F.3d 1345, 1351, 84 USPQ.2d 1034, 1038 (Fed. Cir. 2007) (remanding finding of obviousness by Board of Patent & Appeals under *KSR* for failing to adequately consider secondary evidence of nonobviousness).

Because the analysis applied by the Examiner to the objective evidence was legally flawed, the result cannot stand and requires reversal for this additional reason.

5. The Board should reverse the pending rejection of claims 1-4, 6, 7, 10, 21, and 23-36

There is no *prima facie* case of obviousness because, among other reasons, Lazure teaches away from the proposed combination, and the Examiner's Answer failed to properly rebut Appellant's teaching away argument.

Even if a *prima facie* case of obviousness were presented, which it was not, Appellant's objective evidence of adulation for the invention, commercial success of the invention, and longfelt but unmet need for the invention each individually demonstrate the nonobviousness of the presently claimed invention. When combined, this objective evidence substantively compels a finding of nonobviousness. Moreover, the Office Action's failure to consider any of the objective evidence and further failure to consider alleged *prima facie* case anew in its entirety was improper.

Further still, as explained above, the Office Action individually disregarded Appellant's objective evidence using legally erroneous standards and disregarded Appellant's adulation evidence without any justification whatsoever. Such erroneous disregard for Appellant's evidence requires reversal of the pending obviousness rejection for this procedural defect as well.

Accordingly, Applicant respectfully requests the reversal of the pending obviousness rejection of independent claims 1, 23, and 29, as well as their respective dependent claims, which are patentable at least because they depend from patentable independent claims.

B. The rejection of claims 12, 13, 15-17, 19, 20, 22, and 37-39 under 35 U.S.C. § 103 as obvious over AAPA, the Stevens 1997 article, the Stevens 1999 article, the Franck article, the Seattle Post-Intelligencer article, the Wisconsin State J. article, in view of Lazure further in view of Beckers and Hendriks, Bublit, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine, and further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article.

Appellants also appeal the rejection of claims 12, 13, 15-17, 19, 20, 22, and 37-39 under 35 U.S.C. § 103 as obvious over AAPA, the Stevens 1997 article, the Stevens 1999 article, the Franck article, the Seattle Post-Intelligencer article, the Wisconsin State J. article, in view of Lazure further in view of Beckers and Hendriks, Bublit, further in view of Koch, Corbic, Lane, Sharkey, Stockdale, Meisner, and Christine, and further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article.

1. Claims 12, 13, 15-17, 19, 20, and 22

Independent claim 12 recites, among other things, "preparing a solution comprising sucrose and water; packaging the solution in single-use containers; [and] administering a selected volume dose of the solution orally to the neonatal infant." Independent claim 17 recites, among other things, "providing a solution comprising sucrose and water in an aseptic state and in a volume selected for single patient use within a sealed container; [and] administering the selected dose of the solution to the neonatal infant."

The rejection of independent claims 12 and 17 rests on essentially the same obviousness grounds as asserted against the other claims in this application and discussed above in Subsection I.A. Appellant therefore traverses the obviousness of this combination for essentially the same reasons as discussed above in Subsection I.A. Moreover, the objective evidence discussed above in Subsection I.A.4 likewise compels a finding of nonobviousness of independent claims 12 and 17.

Appellant also traverses this rejection of claims 12 and 17 for an additional reason. Claim 12 recites, among other things, “discarding any residual solution within the opened, individual, single-use container after the planned medical procedure.” Independent claim 17 similarly recites “discarding any residual solution with the container.” In contrast, as explained above in Subsection I.A.1, Lazure’s “unit dose” teaches away from including greater than a unit dose of medicine in a container and teaches away from administering less than the entire unit dose contents of the container. Here, the recited discarding of residual solution is entirely antithetical to Lazure’s “unit dose” teaching, which critically focuses on administering the entire contents of the unit dose container. Thus, Lazure teaches away from the recited combination, and the recited combination is nonobvious for this additional reason.

Accordingly, Appellant respectfully requests the reversal of the pending obviousness rejection of independent claims 12 and 17 , as well as their respective dependent claims, which are patentable at least because they depend from patentable independent claims.

2. Claims 37-39

Independent claim 37 recites, among other things, “providing a cup-shaped container [] defining a cavity[]; transferring the sucrose solution into the cavity of the container; and sealing the container.”

The rejection of independent claim 37 rests on essentially the same obviousness grounds as asserted against the other claims in this application and discussed above in Subsection I.A. Appellant therefore traverses the obviousness of this combination for essentially the same reasons as discussed above in Subsection I.A. Moreover, the objective evidence discussed above in Subsection I.A.4 likewise compels a finding of nonobviousness of independent claim 37.

Accordingly, Appellant respectfully requests the reversal of the pending obviousness rejection of independent claim 37, as well as its dependent claims 38 and 39, which are patentable at least because they depend from patentable independent claims.

II. CONCLUSION

For at least the above reasons, as well as the additional reasons provided in Applicant’s March 20, 2009 Appeal Brief, Applicant respectfully requests the reversal of the pending rejections of claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39.

Having overcome all objections and rejections, Appellant therefore respectfully requests allowance of the present application.

Please charge any fees associated with the submission of this paper to Deposit Account Number 14-1270. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

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